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Incidence And Predictors Of Major Adverse Cardiac Events(mace) Following Drug-eluting Stents Implantation In Patients With Chronic Kidney Disease . Insights From The Desire (Drug-eluting Stents In The Real World) Registry

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Background: Chronic renal disease has been consistently shown to be an independent predictor of poorer long-term clinical outcomes after percutaneous treatment of coronary artery disease, even in DES era. We sought to evaluate the very long-term clinical outcome after DES implantation in this high risk subset in a real world cenario.
Methods and Results: Between May/2002 and May/2010, 3,320 pts treated exclusively with DES were consecutively enrolled in the non-randomized, single-center DESIRE Registry. Recent myocardial infarction (<72h), saphenous venous graft and patients with < 6months follow-up were excluded. The remaining pts (n=2,261) were divided into 2 groups according to their creatinine clearance(CrCl): I-CrCl ≤60 (n= 687) and II- CrCl >60 (n= 1,574). Primary endpoint included combined MACE and stent thrombosis-ARC definitions (ST) rate. Clinical follow-up was obtained at 1, 3 and 6 months and then annually up to 8 years. Follow-up was achieved in 98% of the eligible cohort (median 3.6 years). Baseline characteristics and late outcomes are displayed in the table.

	Clearance ≤ 60 (n=687)	Clearance >60 (n= 1,574)	p
Female gender,%	42.0	16.2	< 0.0001
Age (years)	73.4 ± 8.6	59.6 ± 9.3	<0.0001
Diabetes,%	28.4	28.5	0.96
Unstableangina%	34.5	29.7	0.09
Multivessel disease, %	21.8	22.6	0.66
St / P ratio%	1.53	1.54	0.52
Cumulative events,% Myocardial infarction	6.1	4.3	0.09
TLR	2.7	4.3	0.08
Cardiac death	4.3	1.7	<0.0001
MACE	12.7	9.8	0.05
Stentthrombosis	1.1	0.9	0.29

In the multivariate logistic regression analysis, Age> 75y(OR3.07;95%Confidence interval<CI>1.39 - 6.79, p=0.006), current smoking(OR=3.41CI 1.01-11.5, p=0.04), Diabetes mellitus(OR=2.60CI 1.18-5.72,p=0.017), previous CABG(OR=2.05 CI:1.22 - 3.44,p=0.007), unstable angina(OR=2.17CI:1.16-4.07,p=0.01) and multivessel disease(OR=0.49,CI:0.28-0.86, p=0.001) were independent predictors of mortality.
Conclusions: In the DESIRE Registry the use of DES resulted in very low and equivalent rates of myocardial infarction, TLR and ST even in patients with renal dysfunction. Based on the independent predictors found, we especulate that the higher mortality among these very complex pts may reflect the severity of their co-morbities.

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One Year Outcomes of Patients with Resolute Zotarolimus Eluting Stent: Results of the RESOLUTE International Registry

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Background: The Resolute stent (Medtronic CardioVascular, Santa Rosa, CA) is the next generation zotarolimus-eluting stent that utilizes the BioLinx polymer, a proprietary tripolymer coating that provides gradual elution out to 180 days while maintaining biocompatibility to allow for neointimal healing.
The Resolute stent has been shown to be safe and effective for the treatment of coronary artery disease in the first-in-man trial RESOLUTE and the RESOLUTE All-Comers trial. The purpose of the present registry is to further expand the experience and understanding of the Resolute stent in a 'real-world' setting.
Methods: The RESOLUTE International trial is part of the global Resolute Clinical Program. It is a prospective, multi-center, observational registry, which enrolled over 2200 patients with symptomatic coronary artery disease from 88 centers in Europe, India, South Africa and Argentina. The eligibility criteria were kept comprehensive to reflect routine clinical practice, with no limitations on clinical indication (stable angina vs. acute coronary syndromes), number of treated vessels and lesions, lesion type or lesion length.
The primary endpoint is a composite of cardiac death and (target vessel) myocardial infarction (Q-wave and non-Q-wave) at 12 months. The main secondary endpoint is definite and probable stent thrombosis (ARC defined) at 12 months.
Full monitoring of all patient consents and 25% monitoring of patient source files will be performed. All deaths and reports of myocardial infarctions, stent thrombosis and revascularization events will be adjudicated by an independent Clinical Events Committee. Events are adjudicated according to ARC definitions and expanded historical definitions as defined by a global oversight committee for harmonization of event adjudication in the Resolute Clinical Program.
Results: Patient enrollment took place between 29 August 2008 and 19 March 2009. Currently the 12 months follow-up is being completed, as well as monitoring of the randomly selected patients.
Conclusion: The adjudicated results on the primary endpoint at 12 months will be announced at the time of the meeting.

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Long-term Serial Angiographic Outcomes after Sirolimus-eluting Stent Implantation: Contemporary Practice in Real World Population

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Aim: Percutaneous coronary intervention (PCI) with drug eluting stent (DES) has significantly reduced the rate of repeated target-lesion revascularization. However, the results from a few studies have recently raised concerns regarding 'late catch up' phenomenon of DES. The impact of late restenosis with DES has not been uniform across complex subsets and limited data is available examining predictors of late restenosis in consecutive population.
Method: A total of 3240 lesions were treated with SES from June 2004 to Apr 2007 in our institution. Of those, 306 lesions without restenosis at first follow-up (11.2±2.1 months, range: 9.3~12.4 months) had second follow-up angiography (29.4±5.2 months, range: 24.2~49.2 months). We evaluated the extended term of angiographic outcomes and predictors of late restenosis among patients treated with SES beyond 2 years after the index procedure in unselected consecutive population.
Results: Minimal lumen diameter (MLD) at first angiographic follow-up of overall lesions was significantly smaller compared to that of immediately after procedure (2.72 ± 0.49mm versus 2.83 ± 0.48 mm; p < 0.0001). Also, MLD of overall lesions at second angiographic follow-up was significantly smaller than that of first angiographic follow-up (2.57 ± 0.67 mm versus 2.72 ± 0.49 mm; p < 0.0001). Especially, among patients with late restenosis, MLD was significantly decreased from 28.9 ± 0.42 mm at first angiographic follow-up to 2.41 ± 0.33 mm at second angiographic follow-up (p < 0.0001) , and LL was significantly increased from 0.48 ± 0.27 mm at first angiographic follow-up to 1.23 ± 0.49 mm at second angiographic follow-up (p < 0.0001). There were several predictors identified on univariate analysis such as previous PCI (p = 0.022, OR = 3.938, 95% CI = 1.638-9.464), adjunctive usage of cutting balloon (p = 0.025, OR = 4.051, 95% CI = 1.195-13.727), post-interventional %DS (p = 0.0007, OR = 0.888, 95% CI = 0.829-0.951), and LL (p < 0.0001, OR = 9.255, 95% CI = 4.022-21.296), MLD (p = 0.018, OR = 0.193, 95% CI = 0.069-0.543), %DS (p = 0.0006, OR = 1.070, 95% CI = 1.113) at first angiographic follow up.
Conclusion: Although late regression was observed in BMS era, significant late progression beyond 2 years after SES implantation was observed in the present study. Long term of angiographic follow-up should be recommended to detect 'late-catch up' phenomenon especially in patients with moderate progression at first angiographic follow up.

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Long-term Comparison of Everolimus-Eluting Stents With Sirolimus-Eluting Stents in Patients With Acute Coronary Syndromes

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Background: The long-term safety and efficacy of everolimus-eluting stents (EES) has not been established among patients with acute coronary syndrome (ACS). Moreover, EES have not been directly compared with sirolimus-eluting stents (SES) in large scale clinical trials. We therefore compared the long-term clinical outcome among ACS patients treated with either EES or SES.
Methods: All ACS patients undergoing percutaneous coronary intervention (PCI) with EES between 12/2006 and 03/2009 (N=919) were identified, and clinical outcome compared with 1,216 ACS patients treated with SES. The spectrum of ACS (N=2,135 patients) comprised unstable angina (UA, 10.2%), Non-ST-elevation myocardial infarction (NSTEMI, 55.6%) and ST-elevation myocardial infarction (STEMI, 34.2%). Using propensity score matching, we obtained a total of 1,648 ACS patients with 824 matched pairs of patients treated with EES and SES. The median follow-up was 1.4 years with an accumulated 1,375 patient-years. Hazard ratios comparing EES and SES were calculated using Cox regression analysis.
Results: The median duration of prescribed dual antiplatelet therapy was 12.0 months in both groups. The composite of death, MI or target vessel revascularization (TVR) occurred in 14.3% of EES and 18.7% of SES patients with ACS (HR=0.77, 95% CI 0.60-0.99, p=0.04). The difference in favor of EES was driven by a lower rate of TVR (5.2% vs. 9.3%, p<0.01), whereas rates of death (7.7% vs. 9.6%, p=0.26) or MI (2.8% vs. 4.0%, p=0.23) were similar. The risks of ARC definite (0.2% vs. 2.6%, p<0.01) and definite or probable stent thrombosis (3.4% vs. 6.6%, p<0.01) were lower with EES than SES up to 3 years. Clinical outcome in favor of EES was mostly apparent among patients with STEMI (death, MI, TVR: 12.4% vs. 19.0%, HR=0.69, 95%CI 0.45-1.06) but similar among patients with UA/NSTEMI (17.1% vs. 18.3%, HR=1.0, 95% CI 0.57-1.74, p=1.0).
Conclusion: Among ACS patients, EES is associated with improved efficacy and safety during long-term follow-up to 3 years.

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Comparison of Clinical Outcomes between Zotarolimus-, Sirolimus, and Paclitaxel-eluting Stents in Real Life Clincal Practice

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Background: There are few studies comparing the long term efficacy and safety of the second generation zotarolimus-eluting stents (ZES) with first generation sirolimus- (SES) and paclitaxel-eluting stents (PES) in an unselected cohort that were subject to real life clinical practice.
Methods: Total 2769 patients (mean age 64±11years) who underwent successful PCI with the three DES between April 2006 and July 2008 at two centers, were analyzed retrospectively. 1152 patients were treated with SES, 810 with PES, and 807 with ZES. The primary analysis variable was cumulative rate of target-lesion failure (TLF) at 18months, defined as the composite of cardiac death, target-lesion related myocardial infarction, and ischemia driven target-lesion revascularization (TLR).
Results: Baseline clinical and immediate post-procedure angiographic characteristics were similar in the three groups except for the proportion of patients with acute coronary syndrome, which was higher in the ZES group. TLF rate was significantly lower in the SES group compared with the ZES group (5.6% vs. 9.8%, *P* = 0.001, HR =0.56, CI 0.40 - 0.78), while similar between the PES and ZES group (9.1% vs. 9.8%, *P* = 0.584, HR =0.92, CI 0.67 - 1.26) (Figure 1). This was mostly driven by the higher rate of ischemia-driven TLR in the ZES and PES groups compared with the SES group. The rate of hard endpoints such as the composite of cardiac death and target lesion associated myocardial infarction, or stent thrombosis was similar between the three groups, although numerically was the highest in the ZES group.

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